



CANCER PREVENTION &
RESEARCH INSTITUTE OF TEXAS

December 4, 2012

The Honorable Jane Nelson
P.O. Box 12068
Capitol Station
Austin, Texas 78711

The Honorable James Keffer
CAP 1N.12
P.O. Box 2910
Austin, TX 78768

Dear Senator Nelson and Representative Keffer:

The Cancer Prevention and Research Institute of Texas (CPRIT) has been entrusted with not only improving the lives of cancer patients in Texas but also with the stewardship of public funds. I know that you both are acutely aware of this responsibility as the founding authors of the legislative authority under which we operate.

In early September 2012, I directed the CPRIT chief compliance officer to conduct a top-to-bottom review of the CPRIT-funded companies. The review focused on the grant application and review process each company underwent from application to presentation to the Oversight Committee (OC). During that retrospective review, a serious issue with one company was identified.

Peloton Therapeutics, the Company in question, is a novel research and development platform with several innovative oncology programs. The Column Group, an investment firm, approached CPRIT in June of 2010 in an effort to secure financial support to create Peloton as an early start-up company. The Column Group is an extremely reputable San Francisco biotechnology venture capital firm whose scientific partners include three Nobel Laureates – Michael Brown, M.D., Joel Goldstein, M.D., and David Baltimore, Ph.D., former President of Rockefeller University, and the Founding Director of the Whitehead Institute, as well as Richard Klausner, M.D., the former Director of the National Cancer Institute.

CPRIT's Commercialization program was in its infancy in June 2010 – as a matter of fact Peloton was on the very first commercial grant slate presented to the Oversight Committee two and a half years ago. CPRIT itself was an early start-up, running at full speed to do the best to meet our mandate – staff were being hired, systems were being built, processes were being established and refined, peer reviewers were being recruited and the very best programs for cancer patients in Texas were being identified. Unbeknownst to me, Peloton was placed on an Oversight Committee slate without being formally peer reviewed. My conclusion now is that the placement on the slate of Peloton was a misunderstanding on the part of CPRIT's former Chief Commercialization Officer and that there was no other intent than trying to quickly start efforts to get lifesaving products to Texans with cancer,

Over the course of the retrospective review performed by CPRIT's Chief Compliance Officer the former Chief Commercialization Officer, Mr. Jerry Cobbs, stated that he first heard of Peloton in May or June of 2010 from our former Chief Scientific Officer, Dr. Al Gilman. Dr. Gilman called Mr. Cobbs saying he liked the story of Peloton (named Damascus at the time) and was very enthusiastic about the Project. Following that call there was email correspondence between Mr. Cobbs and Dr. Gilman regarding Peloton. None of these emails are currently available. At some point during this back-and-forth between Mr. Cobbs and Dr. Gilman, a power point of a business plan was forwarded directly to Mr. Cobbs. According to Mr. Cobbs, Peloton at the time had no management team and was a complete start-up – a true company formation. The investment firm wanted to start the company in Texas, associated with UT Southwestern, however Peloton stated that if CPRIT was not interested they would have to consider other locations around the country.

At the time of the Peloton grant, CPRIT did not have specific procedures for company recruitment proposals – as a matter of fact, since Peloton was awarded in mid 2010, CPRIT has not funded any other company recruitments. To put the Peloton award into context, at the time we were considering a continuously open company recruitment RFA (allowing company recruitments to apply anytime). The company recruitment model would have been similar to the CPRIT Scholar recruitment program. Under the Scholar program, recruitment proposals are allowed anytime and reviewed in a timely manner – a monthly peer review meeting is held by the Scientific Review Council – Scholar recruitments are discussed but no scores are given – just an up or down approval. At the Oversight Committee meeting in June 2010, seven CPRIT Scholars were approved totaling \$16 million using this structure. The CPRIT Scholar program uses the same process today. Peloton was treated as a commercial recruitment – as evidenced by its' grant # which begins with an "R" for recruitment. With Peloton there should have been a meeting of the Commercialization Review Council (CRC), which could have happened in a timely fashion, and a recommendation made such that these types of investment opportunities are not lost. There is no documentation that a CRC meeting took place and we must assume the specific recommendation did not happen.

In June 2010, the Chiefs of Prevention, Research and Commercialization, would bring the grant slates recommended by the peer review committees forward to my office. Each of these individuals are subject matter experts in their program areas and I assumed that the best projects were coming forward in the prescribed manner. The grants slates were then placed on a secure web site for review by the Oversight Committee. According to our review, The Chief Commercialization Officer brought Peloton forward on the grant slate under the mistaken notion that he was obtaining approval from the Oversight Committee for permission to perform due diligence on the Company – not for approval to fund, again since Peloton was the first of its type – a company recruitment/formation. In June 2010, detailed peer review comments nor scores were presented to the Oversight Committee at the Board meetings – this has since been changed. This lack of a Commercialization Review Council (CRC) review was never corrected by the Chief Commercialization Officer and did not come to light until the retrospective review.

Peloton received no funding for a year while they secured additional on capital as required for matching by statute. CPRIT's \$11,000,000 grant has been since matched with \$18,000,000 from other investors. Since CPRIT only funds companies in tranches based on performance, Peloton has received \$3,200,000 of the total grant to date. Peloton was not aware that CPRIT processes had not been followed and played no role in placement of the proposal on the award slate.

Funding for Peloton has since been “frozen” and the Company has submitted an application via CPRIT's electronic grants management system in response to a request for commercialization applications (October 28, 2012). CPRIT is requiring Peloton to undergo peer review to comply with the statute. The proposal is currently undergoing this review pursuant to CPRIT's established peer review process. The peer review committee's recommendation to fund or not fund Peloton will determine whether the application is included on a proposed award slate presented to the Oversight Committee. Should Peloton not be recommended for funding or not be ratified by the Oversight Committee, legal remedies will be explored including reimbursement to the State.

Since CPRIT had already identified the Peloton issue ourselves and was taking steps to rectify the problem with either an approved peer review slate or, if Peloton was not approved, a plan for remedy, my plan was to bring the Peloton issue to the Oversight Committee on December 5, 2012.

It is important to note that this error was made during the very early days of CPRIT while the staff was developing and implementing all the checks and balances required for a brand new agency. Since our inception, we have been focused on good stewardship and will continue to do so.

Over the past two and a half years, CPRIT has put in place procedural safeguards that prevent grants being funded without proper steps. Corrective actions include:

- Grant slates presented to the Oversight Committee include peer review critiques and scores – this important information was not provided to the Oversight Committee at the time of Peloton. These peer review critiques and scores documented in the material presented to the Oversight Committee is another check to ensure peer review was conducted (January 2011).
- The on-line grant receipt and award system now incorporates the entire commercialization process – recruitment, formation and relocation. At the time of the Peloton award not all of the commercialization procedures were in place, such as the peer review meeting participation by the contracted Scientific Review Manager for the commercialization program (March 2011).
- The program chiefs for, Prevention, Research, and Commercialization, no longer forward the grant recommendations directly to the Executive Director – a formal certification is required by the Chairs of the peer review committees and is placed in the official record. (March 2012).
- A third party independent review of all peer review committee meetings is performed – an Outside Accounting Firm (Grant Thornton) observes all peer review meetings and documents that CPRIT's grant review policies are followed (May 2012)
- CPRIT hired a Chief Compliance Officer (August 2012).
- The independent 3rd party monitor now reports to the compliance officer (August 2012).
- Academic and commercial review is performed on all company grants – and that review process is now integrated so the academic and commercial experts have the opportunity to exchange expert opinions and reach the best consensus on the merit of the companies to be recommended (October 2012).
- The office of commercialization (and research) is being restructured (November 2012).
- A compliance pedigree consisting of 25 separate process verifications of the receipt and review procedures will be performed on each grant recommended (November 2012).
- The Chief Compliance Officer certifies each grant slate at the time of presentation to the Oversight Committee (December 2012).

CPRIT is still a brand new agency – similar grant making organizations have been in existence for decades. Starting from nothing with a handful of extremely dedicated employees, the Institute has grown into a model for the Nation. In creating a game changing organization from scratch, no doubt a few mistakes were made. As Executive Director, I take great pride in all of our accomplishments but also accept full responsibility for any mistakes,

Sincerely, .



William (Bill) Gimson
Executive Director